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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,181	02/01/2001	Gregory Donoho	LEX-0129-USA	7100

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8800 TECHNOLOGY FOREST PLACE
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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,181

Applicant(s)

DONOHO

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

The Request filed on January 16, 2003 for Continued Examination (RCE) under 37 CFR 1.114 of Application 09/735,712 is granted. An action on the RCE follows.

Applicants' Amendment

Applicants' amendment in Paper No. 16 filed on January 16, 2003 has been entered in full. Claim 2 has been thrice amended. Claims 1-8 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Rejections

The rejection of claim 2 under 35 U.S.C. 112, 2nd paragraph, as set forth in the previous Office Action (Paper No. 7 & 10), has been withdrawn in view of applicants' amendment to the claim.

Claim rejection under 35 U.S.C. § 101

The rejection of claims 1-8 under 35 U.S.C. 101, as set forth in the previous Office Action (Paper No. 7 & 10 and Advisory Action), remains.

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Claims 1-8 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility. The basis for this rejection is set forth in the previous Office Action (Paper No. 7 & 10 and Advisory Action).

Applicants argue that a knockout mouse has been made in which the mouse gene homologous to that represented by SEQ ID NOS: 1 and 2 was disrupted by homologous recombination and such disruption of the mouse gene resulted in an increase in mean cholesterol and triglyceride levels in the blood of male animals, providing evidence that the nucleic acid and protein of the present invention have a biological function and that antagonists directed at the molecule of the present invention can be used to lower blood cholesterol and triglyceride levels, which have been shown to directly lower the risk of heart attacks (2nd paragraph of page 3 of Applicants' response).

This has been fully considered but is not deemed to be persuasive for the following reasons. First, Applicants fail to submit the information and evidence related to the knockout mouse experiment that documents functions of the claimed nucleic acid and protein *in an appropriate form* in which the Examiner may be able to examine the validity of the information and data. Secondly, even if the information had been submitted in an appropriate form, the new evidence on the function of the nucleic acid and protein of the present invention would still have not been found to provide a patentable utility for the instantly claimed invention because there is no support for the

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new information regarding the possible effect of the claimed nucleic acid and protein on blood cholesterol and triglyceride levels. Nowhere in the specification discloses that the nucleic acid and protein have any link with blood cholesterol and triglyceride levels. Therefore, the applicants were not in possession of the utility at the time when the application was filed.

Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph

The rejection of claims 1-8 under 35 U.S.C. §112, 1st Paragraph, as set forth in the previous Office Action (Paper No. 7 & 10 and Advisory Action), remains.

Claims 1-8 are rejected under 35 U. S. C. § 112, 1st paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth in the previous Office Action (Paper No. 7 & 10; Advisory Action).

The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for the reasons set forth above.

Conclusion


No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
March 5, 2003


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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